Patented Medicine Prices Review Board

2015–16

Report on Plans and Priorities

The Honourable Rona Ambrose
Minister of Health

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Chairperson's Message

I am pleased to present the 2015–16 Report on Plans and Priorities for the Patented Medicine Prices Review Board (PMPRB).

The PMPRB is an independent, quasi-judicial administrative agency with a mandate to protect consumers from excessively priced patented medicines. As a member of the Health Portfolio, the PMPRB plays an important role in the broader objective of improving the health of Canadians through a responsible, accessible and sustainable health system.

Canada, like many countries, is facing escalating health care costs, as payers everywhere are struggling to reconcile finite drug budgets with patient access to promising new health technologies. Despite recent stabilizing trends in spending on prescribed drugs, growth in Canadian patented drug sales continues to outpace growth in the seven countries to which we compare ourselves under the *Patented Medicines Regulations*[1] (Regulations), with the exception of the United States. Canadian patented drug prices are now the third highest of these comparator countries, nearly at par with Germany.

The PMPRB was conceived in 1987, through amendments to the *Patent Act*, as part of a major overhaul of Canada's drug patent regime which sought to balance potentially competing policy objectives. On the one hand, the government strengthened patent protection for drugs, in an effort to encourage more pharmaceutical industry research and development (R&D) investment in Canada. On the other, the government sought to mitigate any impact of that change on Canadians by creating the PMPRB, a consumer protection agency with a mandate to ensure patented drug prices in Canada do not become "excessive".

In the ensuing years, intellectual property protection for pharmaceuticals in Canada has been further strengthened through a succession of legislative and regulatory changes[2] while the PMPRB's mandate has remained essentially unchanged. Over the same period, many other developed countries have introduced measures to address affordability issues, maximize value for money and keep pace with a rapidly evolving pharmaceutical market.

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[1] France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States

[2] Bill C-91, *The Patent Act Amendment Act, 1992*, abolished compulsory licensing (which had allowed generic manufacturers to import, make and sell a patented drug before the patent expires) and created the *Patented Medicine (Notice of Compliance)* (PM(NOC) *Regulations* (a special form of patent protection that applies only to pharmaceuticals). In 2001, Bill S-17, an *Act to Amend the Patent Act*, lengthened "term-deficient" patents to comply with a World Trade Organization (WTO) ruling regarding Canada's drug patent regime. In 2006, Canada amended the data protection provisions of the *Food and Drug Regulations* in order to provide new drugs with a guaranteed minimum period of market exclusivity of 8 years.

The upcoming implementation of the Comprehensive Economic and Trade Agreement (CETA) will require amendments to the *Patent Act* to provide pharmaceutical patentees with up to two years of additional market exclusivity. Such a change may precipitate a debate as to whether the current policy balance is working as intended. As that debate unfolds in 2015–16, the PMPRB will examine whether and to what extent changes to its pricing and/or reporting functions are warranted if it is to continue to serve as an effective counterweight to the patent rights of pharmaceutical manufacturers by ensuring that Canadians do not pay excessive prices for patented drugs.

As always, the PMPRB will put the protection of consumer interests first, while recognizing the value that innovative medicines offer to patients.

Mary Catherine Lindberg

Section I: Organizational Expenditure Overview

Organizational Profile

Appropriate Minister: The Honourable Rona Ambrose

Institutional Head: Mary Catherine Lindberg, Chairperson

Ministerial Portfolio: Health

Enabling Instruments: *Patent Act*[i] and *Patented Medicines Regulations*[ii]

Year of Incorporation / Commencement: 1987

Other: The Minister of Health is responsible for the pharmaceutical provisions of the *Patent Act* (Act) set out in sections 79 to 103. The PMPRB is part of the Health Portfolio, which includes Health Canada, the Public Health Agency of Canada, the Canadian Institutes of Health Research and the Canadian Food Inspection Agency. The Health Portfolio supports the Minister of Health in maintaining and improving the health of Canadians.

Although part of the Health Portfolio, the PMPRB carries out its mandate at arm's length from the Minister. It also operates independently of other bodies such as Health Canada, which authorizes the sale of drugs in Canada after their assessment for safety, efficacy and quality; federal, provincial and territorial public drug plans, which are responsible for listing and reimbursement decisions for their respective plans; and the Common Drug Review, administered by the Canadian Agency for Drugs and Technologies in Health (CADTH), which provides listing recommendations to participating public drug plans based on cost-effectiveness.

Organizational Context

Raison d'être

The PMPRB is an independent, quasi-judicial body created by Parliament in 1987. Its mandate is twofold:

- Regulatory – to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive; and
- Reporting – to report on pharmaceutical trends of all medicines and on R&D spending by pharmaceutical patentees.

In carrying out its mandate, the PMPRB ensures that Canadians are protected from excessive prices for patented medicines sold in Canada and that stakeholders are informed on pharmaceutical trends.

Responsibilities

The PMPRB was created as a result of amendments to the *Patent Act* (Act) in 1987 (Bill C-22), and its remedial powers supplemented by further amendments in 1993 (Bill C-91). These amendments were part of policy reforms intended to balance the PMPRB's consumer protection mandate with patent protection measures intended to encourage the R&D efforts of pharmaceutical patentees.

The PMPRB has a dual mandate:

Patented Medicine Prices Regulation

The PMPRB is responsible for ensuring the factory-gate prices that patentees charge for prescription and non-prescription patented medicines sold in Canada to wholesalers, hospitals, pharmacies or others, for human and veterinary use, are not excessive. The PMPRB regulates the price of each patented medicine to which Health Canada has assigned a Drug Identification Number (DIN) as part of its review process. The PMPRB's mandate also includes medicines that are available under the Special Access Programme; through a Clinical Trial Application; and Investigational New Drug Products. Over-the-counter (OTC) patented medicines and patented medicines for veterinary use are regulated by the PMPRB on a complaints basis.

In the event that the Board finds, after a public hearing, that the price of a patented medicine is or was excessive in any market, it may order the patentee to reduce the price and take measures to offset any excess revenues that may have accrued.

Pharmaceutical Trends Reporting

The PMPRB reports annually to Parliament through the Minister of Health on its price review activities, the prices of patented medicines and price trends of all prescription drugs, and on the R&D expenditures reported by pharmaceutical patentees. In addition, as a result of the establishment of the National Prescription Drug Utilization Information System[iii] (NPDUIS) by F/P/T ministers of health in September 2001, the PMPRB conducts critical analysis of price, utilization, and cost trends for patented and non-patented prescription drugs so that Canada's health system has more comprehensive, accurate information on how all prescription drugs are being used and on the sources of cost increases. This function is aimed at providing F/P/T governments and other interested stakeholders with a centralized credible source of information on pharmaceutical trends.

Strategic Outcome(s) and Program Alignment Architecture

1. Strategic Outcome: Canadians are protected from excessive prices for patented medicines sold in Canada and stakeholders are informed on pharmaceutical trends.

1.1 Program: Patented Medicine Prices Regulation Program

1.2 Program: Pharmaceutical Trends Program

Internal Services

Organizational Priorities

Priority	Type[3]	Strategic Outcome and Programs
Address current price and information gaps	New	The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Programs 1.1 and 1.2.

Description

Why is this a priority?

Today's pharmaceutical environment is dynamic and rapidly evolving. As a micro agency with a small but agile workforce, the PMPRB is well equipped to respond to the changes in its environment by adjusting its regulatory and reporting practices from year to year in a manner that best serves its consumer protection mandate. Since 2010, public payers in Canada have made significant progress in their efforts to secure price reductions from pharmaceutical manufacturers by harnessing the combined purchasing power of the provinces and territories through the pan-Canadian Pharmaceutical Alliance (pCPA)[iv]. While the PMPRB has sought to support these efforts through its reporting function by providing public payers with pricing information and analytics, the success of the pCPA in bringing down prices raises legitimate questions about how the PMPRB's price regulation function can continue to support provincial and territorial governments. However, private payers, who are responsible for the majority of pharmaceutical expenditures in Canada, do not benefit from pCPA-negotiated price reductions. Moreover, those least able tend to pay the highest prices in Canada, with one in ten consumers said to be unable to afford their prescriptions. One issue of considerable concern to public and private payers alike is industry's current focus on niche drugs that can offer significant therapeutic benefit but at very high cost.

What are the plans for meeting this priority?

On the regulatory side, the PMPRB will:

- seek out opportunities to address instances of excessive pricing in the form of price discrimination and market segmentation.

On the reporting side, the PMPRB will:

- intensify its partnership with public payers to provide ever more timely and relevant pricing information; and
- expand the scope of pharmaceutical topics on which it reports to provide private payers and consumers with information to help them make better, more cost effective choices.

[3] Type is defined as follows: previously committed to—committed to in the first or second fiscal year prior to the subject year of the report; ongoing—committed to at least three fiscal years prior to the subject year of the report; and new—newly committed to in the reporting year of the RPP or DPR.

Priority	Type	Strategic Outcome and Programs
Increase Public Awareness	New	The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Programs 1.1 and 1.2.

Description

Why is this a priority?

In order to be fully informed of, and respond to, the relevant changes in its environment, the PMPRB must engage with a heterogeneous network of pharmaceutical industry stakeholders, each with its own unique interest and perspective on these changes. To do so effectively, the PMPRB must enhance awareness of its consumer protection mandate and build on its honest broker reputation with stakeholders and the public at large.

What are the plans for meeting this priority?

The PMPRB will:

- adopt a more proactive approach to communicating its regulatory and reporting achievements to stakeholders and the public;
- look for opportunities to leverage strategic partnerships; and
- broaden the scope of pharmaceutical issues on which it reports.

Priority	Type	Strategic Outcome and Programs
Regulatory Modernization	New	The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Programs 1.1 and 1.2.

Description

Why is this a priority?

In Canada, public payers are increasingly entering into confidential product listing agreements (PLA's) with pharmaceutical manufacturers, either individually or under the auspices of the pCPA. This complicates the PMPRB's ability to ascertain the true price of a drug, and may result in upward pressure on prices in the private market. As other countries experiment with new cost control methods, Canadian patented drug prices are rising relative to the seven other countries to which Canada compares itself under the *Patented Medicines Regulations*. Canada's recent commitment under the Comprehensive Economic Trade Agreement (CETA) with the EU to amend the *Patent Act* to extend the terms of pharmaceutical patents by up to two years may precipitate a debate over the appropriate balance between intellectual property rights and consumer protection.

What are the plans for meeting this priority?

The PMPRB will examine whether and to what extent changes to its pricing and/or reporting functions are warranted if it is to continue to meet its strategic outcome of ensuring that Canadians do not pay excessive prices for patented drugs.

Priority	Type	Strategic Outcome and Programs
Employee engagement and organizational synergy	New	The PMPRB has only one SO and all risks are linked to that SO. This priority is linked to Programs 1.1 and 1.2.

Description

Why is this a priority?

In response to feedback from the 2011 Public Service Employee Survey and a succession planning report produced by independent experts, the PMPRB has initiated a process to engage staff and obtain their input and buy in on the PMPRB's strategic direction and priorities over the next three years. As part of that process, staff will gain a better understanding of the PMPRB's operational framework and how the work of each branch contributes to the achievement of the organization's strategic outcome.

What are the plans for meeting this priority?

The PMPRB will focus on:

- clearer and more structured communication between and among management and staff;
- greater internal collaboration:
- better integrating its business processes; and
- optimal utilization of its diverse employee skill sets.

Risk Analysis

Key Risks

Risk	Risk Response Strategy	Link to Program Alignment Architecture
As the provinces and territories move to formalize the pCPA and achieve even greater price reductions from pharmaceutical manufacturers, there is a risk that the price ceilings set by the PMPRB will become increasingly irrelevant to public payers.	• The PMPRB will intensify its partnership with public payers to better anticipate their market intelligence requirements and provide ever more timely and relevant information and analytics to the pCPA. • The PMPRB will conduct targeted regulatory interventions that focus on instances of excessive pricing in the form of price discrimination and/or market segmentation in an effort to close the gap between public and private prices	The PMPRB has only one SO and all risks are linked to that SO.
There is a risk that continued efforts by pharmaceutical pricing and reimbursement authorities in the EU to lower prices will soon result in Canada having the second highest patented drug prices, below only the US, of the PMPRB's seven comparator countries and/or prices that are higher than the international median.	• The PMPRB will examine whether and to what extent changes to its consumer protection powers are needed to ensure that Canadians are paying a fair price for patented medicines. • The PMPRB will strengthen ties with pricing and reimbursement authorities in other countries to share market intelligence and stay abreast of the latest developments.	The PMPRB has only one SO and all risks are linked to that SO.
Implementation of the CETA may precipitate a debate on whether the balance between patent protection and consumer protection is working as intended.	• The PMPRB will examine whether and to what extent changes to its consumer protection powers are needed to ensure that Canadians are paying a fair price for patented medicines.	The PMPRB has only one SO and all risks are linked to that SO.
Impact of pending litigation on the PMPRB's jurisdiction	On June 25, 2014, the Attorney General filed Notices of Appeal in respect of two decisions of the Federal Court of Canada issued on on May 27, 2014, relating to the Board's jurisdiction over certain drug products sold by Ratiopharm Inc. (now Teva Canada Limited) and Sandoz Canada Inc..	The PMPRB has only one SO and all risks are linked to that SO.

Risk	Risk Response Strategy	Link to Program Alignment Architecture
Given the highly specialized nature of its consumer protection mandate, the PMPRB depends on its ability to attract and retain subject matter experts.	The PMPRB has made employee engagement one of its four strategic priorities and is in the process of hiring new staff with the skill sets to advance its priorities.	The PMPRB has only one SO and all risks are linked to that SO.

As in past years, many countries continue to struggle with rising health care costs. Recent changes to foreign and domestic pharmaceutical regulatory systems have focused on cost containment measures. The PMPRB continues to monitor and assess the impact of foreign and domestic changes to pharmaceutical regulatory systems on its price review process.

Canada's recent commitment under CETA to amend the *Patent Act* to extend the terms of pharmaceutical patents by up to two years may precipitate a debate over the appropriate balance between intellectual property rights and consumer protection. As a result, the PMPRB's price regulation program may come under increased scrutiny.

While the PMPRB's legal framework has remained essentially unchanged since 1987, regimes in many other developed countries have undergone significant changes in order to address issues of affordability and to keep pace with a rapidly evolving pharmaceutical market. In 2015–16, the PMPRB will examine whether and to what extent similar changes to its consumer protection powers are needed.

As the federal expert body on questions related to drug prices, the PMPRB, via its Pharmaceutical Trends Program, contributes to informed decision-making by reporting on pharmaceutical trends. In addition, the PMPRB undertakes studies and conducts analysis on a variety of topics related to pharmaceutical pricing and costs. Through critical analyses of price, utilization and cost trends conducted under the NPDUIS initiative, the PMPRB provides Canada's health system with comprehensive and accurate information on how prescription drugs are being used and on cost drivers. Since 2013–14 the PMPRB has focused on strategies to improve the efficiency and relevance of its reporting mandate. In order to enhance the relevance of NPDUIS reporting, the PMPRB has embarked on a broader engagement strategy to identify research priorities and emerging areas of interest. The PMPRB has increased its outreach efforts with key stakeholders including academics, federal health portfolio partners, government policy and research communities, pharmaceutical and insurance industry as well as health professionals, patient advocacy and consumer groups. In 2015–16, the PMPRB will intensify its partnership with public payers to provide ever more timely and relevant pharmaceutical information and analytics. Similarly, it will expand the scope of pharmaceutical topics it reports on to provide

private payers and consumers with information to help them make better, more cost effective choices.

Given the highly specialized nature of its consumer protection mandate, the PMPRB must continue to attract and retain subject matter experts. Creating a culture that values employees and recognizes and rewards their contributions in a variety of ways is a key strategy to attracting and retaining top performers. To be a successful organization, the PMPRB must engage its employees to perform at their best by creating a culture of recognition, which is performance focused. In 2015–16, the PMPRB will implement a number of staff-initiated measures aimed at achieving greater internal collaboration, better integrating business processes and capitalizing on its employees' deep and diverse skill sets.

Planned Expenditures

Budgetary Financial Resources (dollars)

2015–16 Main Estimates	2015–16 Planned Spending	2016–17 Planned Spending	2017–18 Planned Spending
10,945,181	10,945,181	10,945,181	10,945,181

Human Resources (Full-Time Equivalents [FTEs])

2015–16	2016–17	2017–18
71	71	71

Budgetary Planning Summary for Strategic Outcome(s) and Program(s) (dollars)

Strategic Outcome(s), Program(s) and Internal Services	2012–13 Expenditures	2013–14 Expenditures	2014–15 Forecast Spending	2015–16 Main Estimates	2015–16 Planned Spending	2016–17 Planned Spending	2017–18 Planned Spending
Strategic Outcome 1: Canadians are protected from excessive prices for patented medicines sold in Canada and stakeholders are informed on pharmaceutical trends.							
Patented Medicine Prices Regulation Program	3,888,795	*6,395,602	3,636,684	**6,834,096	6,834,096	6,834,096	6,834,096
Pharmaceutical Trends Program	983,279	1,146,790	1,391,086	1,506,994	1,506,994	1,506,994	1,506,994
Subtotal	4,872,074	7,542,392	5,027,770	8,341,090	8,341,090	8,341,090	8,341,090
Internal Services Subtotal	3,184,729	2,998,175	3,198,053	2,604,091	2,604,091	2,604,091	2,604,091
Total	8,056,803	10,540,567	8,225,823	10,945,181	10,945,181	10,945,181	10,945,181

* Expenditures for 2013–14 were significantly higher than expenditures in 2012–13 and 2014–15. This variance is due in large part to a Federal Court decision that quashed a Board Order and directed the PMPRB return to the patentee the sum of $2,801,275 paid to the Board as a payment of excess revenues earned, plus appropriate interest and costs.

** Planned spending in 2015–16 and future years is based on the assumption that the PMPRB will spend the full $2.47 million held in the SPA reserved for conducting public hearings. This is done because these expenditures are dependent on the number of hearings, and the length and complexity of the hearings held, which are difficult to predict.

Alignment of Spending With the Whole-of-Government Framework

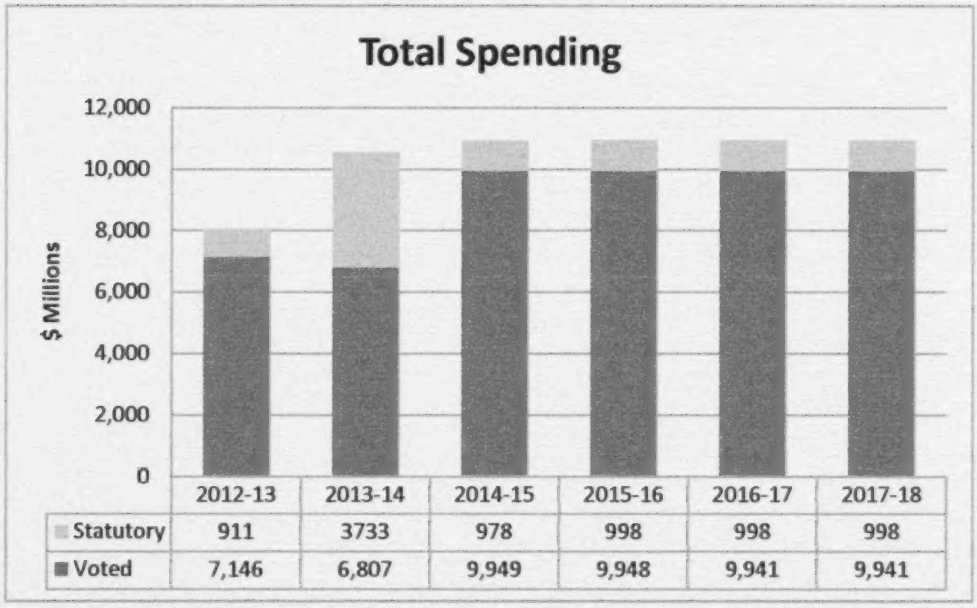
Alignment of 2015–16 Planned Spending With the Whole-of-Government Framework[v] (dollars)

Strategic Outcome	Program	Spending Area	Government of Canada Outcome	2015–16 Planned Spending
Canadians are protected from excessive prices for patented medicines sold in Canada and stakeholders are informed on pharmaceutical trends.	Patented Medicine Prices Regulation Program	Social affairs	Healthy Canadians	6,834,096
	Pharmaceutical Trends Program	Social affairs	Healthy Canadians	1,506,994

Total Spending by Spending Area (dollars)

Spending Area	Total Planned Spending
Economic affairs	
Social affairs	8,341,090
International affairs	
Government affairs	

Departmental Spending Trend



	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Statutory	911	3733	978	998	998	998
Voted	7,146	6,807	9,949	9,948	9,941	9,941

The variance between the Expenditures for 2012–13 and 2013–14 is largely due to additional funding received through an adjustment warrant to cover the amount ordered by the Federal Court to refund to a patentee. The Federal Court quashed a Board Order and directed in its judgement that a payment of excess revenues in the sum of $2,801,285 be returned by the PMPRB to the patentee with appropriate interest and specified costs.

The 2015–16 Main Estimates amount includes funding for a Special Purpose Allotment (SPA) in the amount of $2,470,000. The SPA is for conducting Public Hearings and can only be used to cover costs such as external legal counsel, expert witnesses, etc. Any unspent SPA funds are returned to the Consolidated Revenue Fund (CRF).

Due to challenges related to forecasting the number and complexity of hearings, for purposes of forecasting Planned Spending for 2015–16 and future years it is assumed that the entire SPA funding will be spent.

Estimates by Vote

For information on PMPRB's organizational appropriations, consult the *2015–16 Main Estimates* on the Treasury Board of Canada Secretariat website.[vi]

Section II: Analysis of Program(s) by Strategic Outcome

Strategic Outcome:

Canadians are protected from excessive prices for patented medicines sold in Canada and stakeholders are informed on pharmaceutical trends.

Program 1.1: Patented Medicine Prices Regulation Program

Description

The PMPRB is an independent quasi-judicial body that is responsible for ensuring that the prices that patentees charge for patented medicines sold in Canada are not excessive based on the price review factors in the *Patent Act* (Act). To make this determination the Board must consider each of the following factors: prices at which the medicine and other medicines in the same therapeutic class have been sold in Canada and in the seven comparator countries listed in the *Patented Medicines Regulations* (Regulations); changes in the Consumer Price Index (CPI); and in accordance with the Act, such other factors as may be specified in any regulations made for the purposes of the price review. Under the Act, and as per the Regulations, patentees are required to file price and sales information for each patented medicine sold in Canada, for the duration of the patent(s). Board Staff reviews the introductory and ongoing information filed by patentees, for all patented medicines sold in Canada. When it finds that the price of a patented medicine appears to be excessive, Board Staff will conduct an investigation into the price. An investigation could result in: its closure, where it is concluded that the price was non-excessive; a Voluntary Compliance Undertaking (VCU) by the patentee to reduce the price and offset excess revenues obtained as a result of excessive prices through a payment and/or a price reduction of another patented drug product; or a public hearing to determine if the price is excessive, including any remedial order determined by the Board. In the event that the Board Hearing Panel finds, after a public hearing, that a price is or was excessive, it may order the patentee to reduce the price and take measures to offset any excess revenues. This program, by reviewing the prices charged by patentees for patented medicines sold in Canada, protects Canadians and the health care system from excessive prices.

Budgetary Financial Resources (dollars)

2015–16 Main Estimates	2015–16 Planned Spending	2016–17 Planned Spending	2017–18 Planned Spending
6,834,096	6,834,096	6,834,096	6,834,096

Human Resources (Full-Time Equivalents [FTEs])

2015–16	2016–17	2017–18
42	42	42

Performance Measurement

Expected Results	Performance Indicators	Targets	Date to Be Achieved
Patentees comply with the *Patent Act*, the Regulations, and the Excessive Price Guidelines (Guidelines)	Percentage of patented medicines that are priced, as a result of voluntary compliance, within the Guidelines or at a price which does not trigger the investigation criteria	95%	March 31 of each year
	Percentage of compliance with Board Orders related to price and/or jurisdiction and with Voluntary Compliance Undertakings (VCUs)	100%	March 31 of each year
Canadian prices for patented medicines are on average in line with prices in the seven comparator countries listed in the Regulations	Canadian prices for new patented medicines are, on average, at or below the median of international prices	100%	March 31 of each year
	Canadian prices for existing patented medicines are on average at or below the median of international prices	100%	March 31 of each year

Planning Highlights

The PMPRB will conduct targeted regulatory interventions which focus on instances of excessive pricing in the form of price discrimination and market segmentation in an effort

to close the gap between public and private prices, particularly with respect to high cost biologic/orphan drugs. The PMPRB will examine whether and to what extent changes to its regulatory and/or reporting functions are warranted if it is to continue to meet its strategic outcome of ensuring that Canadians do not pay excessive prices for patented drug products.

Program 1.2: Pharmaceutical Trends Program

Description

The PMPRB reports annually to Parliament through the Minister of Health on its price review activities, the prices of patented medicines and price trends for all drugs, and R&D expenditures as reported by pharmaceutical patentees. In supporting this requirement, the pharmaceutical trends program provides complete and accurate information on trends in manufacturers' prices of patented medicines sold in Canada and on patentees' research-and-development expenditures to interested stakeholders including: industry (i.e., brand-name, biotech, generic); federal, provincial and territorial (F/P/T) governments; consumer and patient advocacy groups; third party payers; and others. This information also provides assurance to Canadians that the prices of patented medicines are not excessive. In addition, as a result of the establishment of the NPDUIS by F/P/T ministers of health the Federal Minister of Health requested that the PMPRB conduct analysis of price, utilization and cost trends for patented and non-patented prescription drugs so that Canada's health system has more comprehensive, accurate information on how all prescription drugs are being used and on the sources of cost increases. This function is aimed at providing F/P/T governments and other interested stakeholders with a centralized credible source of information on all prescription drug prices.

Budgetary Financial Resources (dollars)

2015–16 Planned Spending	2016–17 Planned Spending	2017–18 Planned Spending
1,506,994	1,506,994	1,506,994

Human Resources (FTEs)

2015–16	2016–17	2017–18
10	10	10

Performance Measurement

Expected Results	Performance Indicators	Targets	Date to Be Achieved
Information on pharmaceutical trends and cost drivers is available to stakeholders	Number of new reports/studies posted on the PMPRB website	12 reports/studies	March 31 each year
	Number of presentations made by the PMPRB to an external audience	10 information sessions	March 31 each year

Planning Highlights

The PMPRB will adopt a more proactive approach to communicating its regulatory and reporting achievements to the public and will build on its reputation as an honest broker in identifying, analyzing and reporting on pharmaceutical issues. This includes intensifying its partnership with public payers to provide ever more timely and relevant pricing information and analytics, expanding the scope of pharmaceutical topics on which it reports to provide private payers and consumers with information to help them make better more cost effective choices. Finally, the PMPRB will strengthen ties with pricing and reimbursement authorities in other countries in order to share market intelligence and stay abreast of the very latest developments in this area. The PMPRB will also continue to publish its NPDUIS Research Agenda which reflects the priorities identified by the NPDUIS Advisory Committee and lists the reports anticipated for completion and publication each year.

Internal Services

Description

Internal Services are groups of related activities and resources that are administered to support the needs of programs and other corporate obligations of an organization. Internal services include only those activities and resources that apply across an organization, and not those provided to a specific program. The groups of activities are: Management and Oversight Services; Communications Services; Legal Services; Human Resources Management Services; Financial Management Services; Information Management Services; Information Technology Services; Real Property Services; Materiel Services; and Acquisition Services.

Budgetary Financial Resources (dollars)

2015–16 Main Estimates	2015–16 Planned Spending	2016–17 Planned Spending	2017–18 Planned Spending
2,604,091	2,604,091	2,604,091	2,604,091

Human Resources (FTEs)

2015–16	2016–17	2017–18
19	19	19

Planning Highlights

The PMPRB will be implementing a number of measures suggested by staff in order to achieve greater internal collaboration, better integrate its business processes and better utilize its deep, diverse skill sets to meet its strategic outcomes. It will also provide for greater management accountability in this area by providing staff with an opportunity to formally input on the degree to which they feel their managers are championing these measures in their respective branches.

Section III: Supplementary Information

Future-Oriented Statement of Operations

The future-oriented condensed statement of operations provides a general overview of the PMPRB's operations. The forecast of financial information on expenses and revenues is prepared on an accrual accounting basis to strengthen accountability and to improve transparency and financial management.

Because the future-oriented condensed statement of operations is prepared on an accrual accounting basis, and the forecast and planned spending amounts presented in other sections of the Report on Plans and Priorities are prepared on an expenditure basis, amounts differ.

A more detailed future-oriented statement of operations and associated notes[vii], including a reconciliation of the net cost of operations to the requested authorities, can be found on the Patented Medicine Prices Review Board's website

Future-Oriented Condensed Statement of Operations
For the Year Ended March 31
(dollars)

Financial Information	2014–15 Estimated Results	2015–16 Planned Results	Difference
Total expenses	9,161,120	12,016,985	2,855,865
Total revenues[1]			
Net cost of operations	9,161,120	12,016,985	2,855,865

[1] The PMPRB collects non-respendable revenue as a result of payments made by patentees to the Government of Canada through Voluntary Compliance Undertakings (VCUs) or Board Orders to offset excess revenues. The Minister may enter into agreements with any province or territory respecting the distribution to that province/territory of amounts received by the Receiver General, less any costs incurred in relation to the collection and distribution of those amounts. As at December 31, 2014, the PMPRB collected $2,157,475 in non-respendable revenue. Revenues that are non-respendable are not available to discharge the PMPRB's liabilities. While the Deputy Head is expected to maintain accounting control, she has no authority regarding the disposition of non-respendable revenues. As a result, non-respendable revenues are considered to be earned on behalf of the Government of Canada and are therefore presented in reduction of the entity's gross revenues

Supplementary Information Tables

The supplementary information tables[viii] listed in the *2015–16 Report on Plans and Priorities* can be found on the Patented Medicine Prices Review Board's website.

- Departmental Sustainable Development Strategy[ix]; and
- Upcoming Internal Audits and Evaluations Over the Next Three Fiscal Years[x].

Tax Expenditures and Evaluations

The tax system can be used to achieve public policy objectives through the application of special measures such as low tax rates, exemptions, deductions, deferrals and credits. The Department of Finance Canada publishes cost estimates and projections for these measures annually in the *Tax Expenditures and Evaluations*[xi] publication. The tax measures presented in the *Tax Expenditures and Evaluations* publication are the responsibility of the Minister of Finance.

Section IV: Organizational Contact Information

The Patented Medicine Prices Review Board
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Appendix: Definitions

appropriation: Any authority of Parliament to pay money out of the Consolidated Revenue Fund.

budgetary expenditures: Include operating and capital expenditures; transfer payments to other levels of government, organizations or individuals; and payments to Crown corporations.

Departmental Performance Report: Reports on an appropriated organization's actual accomplishments against the plans, priorities and expected results set out in the corresponding Reports on Plans and Priorities. These reports are tabled in Parliament in the fall.

full-time equivalent: Is a measure of the extent to which an employee represents a full person-year charge against a departmental budget. Full-time equivalents are calculated as a ratio of assigned hours of work to scheduled hours of work. Scheduled hours of work are set out in collective agreements.

Government of Canada outcomes: A set of 16 high-level objectives defined for the government as a whole, grouped in four spending areas: economic affairs, social affairs, international affairs and government affairs.

Management, Resources and Results Structure: A comprehensive framework that consists of an organization's inventory of programs, resources, results, performance indicators and governance information. Programs and results are depicted in their hierarchical relationship to each other and to the Strategic Outcome(s) to which they contribute. The Management, Resources and Results Structure is developed from the Program Alignment Architecture.

non-budgetary expenditures: Include net outlays and receipts related to loans, investments and advances, which change the composition of the financial assets of the Government of Canada.

performance: What an organization did with its resources to achieve its results, how well those results compare to what the organization intended to achieve and how well lessons learned have been identified.

performance indicator: A qualitative or quantitative means of measuring an output or outcome, with the intention of gauging the performance of an organization, program, policy or initiative respecting expected results.

performance reporting: The process of communicating evidence-based performance information. Performance reporting supports decision making, accountability and transparency.

planned spending: For Reports on Plans and Priorities (RPPs) and Departmental Performance Reports (DPRs), planned spending refers to those amounts that receive Treasury Board approval by February 1. Therefore, planned spending may include amounts incremental to planned expenditures presented in the Main Estimates.

A department is expected to be aware of the authorities that it has sought and received. The determination of planned spending is a departmental responsibility, and departments must be able to defend the expenditure and accrual numbers presented in their RPPs and DPRs.

plans: The articulation of strategic choices, which provides information on how an organization intends to achieve its priorities and associated results. Generally a plan will explain the logic behind the strategies chosen and tend to focus on actions that lead up to the expected result.

priorities: Plans or projects that an organization has chosen to focus and report on during the planning period. Priorities represent the things that are most important or what must be done first to support the achievement of the desired Strategic Outcome(s).

program: A group of related resource inputs and activities that are managed to meet specific needs and to achieve intended results and that are treated as a budgetary unit.

Program Alignment Architecture: A structured inventory of an organization's programs depicting the hierarchical relationship between programs and the Strategic Outcome(s) to which they contribute.

Report on Plans and Priorities: Provides information on the plans and expected performance of appropriated organizations over a three-year period. These reports are tabled in Parliament each spring.

results: An external consequence attributed, in part, to an organization, policy, program or initiative. Results are not within the control of a single organization, policy, program or initiative; instead they are within the area of the organization's influence.

Strategic Outcome: A long-term and enduring benefit to Canadians that is linked to the organization's mandate, vision and core functions.

sunset program: A time-limited program that does not have an ongoing funding and policy authority. When the program is set to expire, a decision must be made whether to continue the program. In the case of a renewal, the decision specifies the scope, funding level and duration.

target: A measurable performance or success level that an organization, program or initiative plans to achieve within a specified time period. Targets can be either quantitative or qualitative.

whole-of-government framework: Maps the financial contributions of federal organizations receiving appropriations by aligning their Programs to a set of 16 government-wide, high-level outcome areas, grouped under four spending areas.

Endnotes

[i] *Patent Act:* http://laws-lois.justice.gc.ca/eng/acts/P-4/

[ii] *Patented Medicines Regulations:* http://laws.justice.gc.ca/en/P-4/SOR-94-688/index.html

[iii] Additional information on the National Prescription Drug Utilization Information System can be found on the PMPRB website: http://www.pmprb-cepmb.gc.ca/en/npduis/about-npduis

[iv] Additional information on the pan-Canadian Pharmaceutical Alliance can be found at: http://www.conseildelafederation.ca/en/initiatives/358-pan-canadian-pricing-alliance

[v] Whole-of-government framework, http://www.tbs-sct.gc.ca/ppg-cpr/frame-cadre-eng.aspx

[vi] *2015–16 Main Estimates*, http://publiservice.tbs-sct.gc.ca/ems-sgd/esp-pbc/me-bpd-eng.asp

[vii] A more detailed future-oriented statement of operations and associated notes , including a reconciliation of the net cost of operations to the requested authorities, can be found on the PMPRB's website: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=899&lang=en

[viii] The supplementary information tables listed in the 2014–15 Report on Plans and Priorities can be found on the Patented Medicine Prices Review Board's website: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=889

[ix] Departmental Sustainable Development Strategy: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=889

[x] Upcoming Internal Audits and Evaluations Over the Next Three Fiscal Years: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=889

[xi] *Tax Expenditures and Evaluations* publication, http://www.fin.gc.ca/purl/taxexp-eng.asp